

K970090

APR 21 1997

Premarket Notification 510(k) Summary

[As required by Section 807.92 (c)]

S O L O - S L E D , L L C

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Trade Name: Solo-Sled
Common Name: Cassette Positioner
Classification Name: Accessory to
Radiographic Film
Cassette

Description of device: Solo-Sled is a device made from an artifact free (ABS) plastic - acrylonitrile butadiene styrene which is injection molded. It has a smooth low resistance outer finish with reinforced edges for extra strength and patient comfort. It has two handles for ease of positioning by staff members. It has dimensions to accommodate a 14 x 17 cassette.

Intended Use of Device: Solo-Sled is a device designed to allow one staff member to be able to position 14 x 17 cassettes behind chest and/or under the back of a patient without causing pain to the patient in lifting or moving them. Solo-Sled will allow positioning of cassettes without requiring two to three staff members to lift the patient once to place the cassette and then the second time to remove the cassette. The device is an accessory to a 14 x 17 radiographic film cassette.

Substantial Equivalence Comparison

**Substantial Equivalence: Radiographic
Film Cassette**

The standard radiographic film cassettes are rectangular in design with hard, flat, square corners making them difficult to position or slide under a patient receiving a portable radiographic examination. Routinely, the patient is moved, pulled and tugged to position the 14 x 17 cassette. Portable radiographic examinations are performed on critically ill or terminal patients. In addition the process routinely requires two to three healthcare providers to lift the patient to place the cassette into position.

The Solo-Sled provides a "sleeve" with round edges and corners that houses the 14 x 17 radiographic cassette which is aerodynamic in design. It has low surface resistance which enables a single technologist to simply slide the cassette into position and remove the cassette by sliding Solo-Sled up and out.

Performance

Safety and Effectiveness:

The Solo-Sled is made from high impact (ABS) plastic, Acrylonitrile Butadiene Styrene, which poses no health risk either by contact or use with patients. In addition, it does not possess properties that would irritate the skin, nor does it have the potential to be abrasive to the skin during use. A copy of the Material Safety Data Sheet (MSDS) is included for your reference.

The Solo-Sled device does not alter the radiographic image quality, create image distortion and is artifact free. The radiographic image quality and technical factors remain the same with and without the use of the Solo-Sled. The physics testing and findings are included for your reference.

In summary the Solo-Sled is a safe and effective device to position and remove a 14 x 17 radiographic cassette for portable radiographic examinations on critically ill and terminal patients.